UMC Utrecht

Why the NICE AAA Guidelines favouring open repair over EVAR are the way they are: bias has played a role as it does in many things: Randomized Controlled Trials (RCT's) can be misleading. the way they are: bias has played a role as it does in many things: Randomized Controlled Trials (RCTs) can be misleading

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UMC Utrecht

## DISCLOSURES

"No Disclosures"



## Bias & Randomized Controlled Trial

Bias is a partiality that prevents objective consideration of an issue or situation

So, when a Guideline-Committee is biased, it means that they are unable to consider an issue or situation objectively

## NICE 2020 guidelines were mainly based on the results of EVAR 1 & 2

To write a Guideline for EVAR evaluation you need to check:

- Is there a special (hybrid) setting in the OR for optimal results
- When the physician responsible has no experience with a new technology, it is mandatory that the first cases are done under supervison of an experienced physician
- the majority of the committee members of the NICE guidelines were biased because they were unable for objective information (no experts in EVAR were invited)

## Analysis of the Differences Between the ESVS 2019 and NICE 2020 Guidelines for Abdominal Aortic Aneurysm

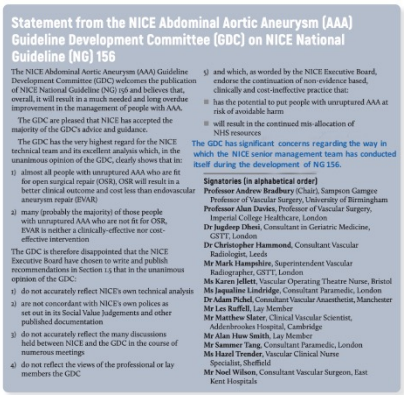
*For debate/Volume 60, Issue 1, P7-15, July 01, 2020. EJVES 2020*

Objective: The aim was to understand why two recently published guidelines for the diagnosis and management of patients with abdominal aortic aneurysm, the National Institute for Health and Care Excellence (NICE) 2020 guidelines and the European Society for Vascular Surgery (ESVS) 2019 guidelines, have discordant recommendations in several important areas

## Results

NICE recommends an open first strategy for non-ruptured AAA mainly based on earlier RCTs and UK specific economic modelling, while the ESVS guidelines recommend an EVAR first strategy after consideration of modern, but lower quality, evidence from observational studies.

Similar reasons explain differences in the recommended treatments of juxtarenal aneurysms



**Statement from the NICE Abdominal Aortic Aneurysm (AAA) Guideline Development Committee (GDC) on NICE National Guideline (NG) 156**

The NICE Abdominal Aortic Aneurysm (AAA) Guideline Development Committee (GDC) welcomes the publication of NICE National Guideline (NG) 156 and believes that, overall, it will result in a much needed and long overdue improvement in the management of people with AAA.

The GDC are pleased that NICE has accepted the majority of the GDC's advice and guidance.

The GDC has the very highest regard for the NICE technical team and its excellent analysis which, in the unanimous opinion of the GDC, clearly shows that in:

1) almost all people with unruptured AAA who are fit for open surgical repair (OSR), OSR will result in a better clinical outcome and cost less than endovascular aneurysm repair (EVAR)
2) many (probably the majority) of those people with unruptured AAA who are not fit for OSR, EVAR is neither a clinically-effective nor cost-effective intervention

The GDC is therefore disappointed that the NICE Executive Board have chosen to write and publish recommendations in Section 1.5 that in the unanimous opinion of the GDC:

1) do not accurately reflect NICE's own technical analysis
2) are not concordant with NICE's own polices as set out in its Social Value Judgements and other published documentation
3) do not accurately reflect the many discussions held between NICE and the GDC in the course of numerous meetings
4) do not reflect the views of the professional or lay members the GDC
5) and which, as worded by the NICE Executive Board, endorse the continuation of non-evidence based, clinically and cost-ineffective practice that:
   - has the potential to put people with unruptured AAA at risk of avoidable harm
   - will result in the continued mis-allocation of NHS resources

**The GDC has significant concerns regarding the way in which the NICE senior management team has conducted itself during the development of NG 156.**

**Signatories (in alphabetical order)**
**Professor Andrew Bradbury** (Chair), Sampson Gamgee Professor of Vascular Surgery, University of Birmingham
**Professor Alun Davies**, Professor of Vascular Surgery, Imperial College Healthcare, London
**Dr Jugdeep Dhesi**, Consultant in Geriatric Medicine, GSTT, London
**Dr Christopher Hammond**, Consultant Vascular Radiologist, Leeds
**Mr Mark Hampshire**, Superintendent Vascular Radiographer, GSTT, London
**Ms Karen Jellett**, Vascular Operating Theatre Nurse, Bristol
**Ms Jaqualine Lindridge**, Consultant Paramedic, London
**Dr Adam Pichel**, Consultant Vascular Anaesthetist, Manchester
**Mr Les Ruffell**, Lay Member
**Mr Matthew Slater**, Clinical Vascular Scientist, Addenbrookes Hospital, Cambridge
**Mr Alan Huw Smith**, Lay Member
**Mr Sammer Tang**, Consultant Paramedic, London
**Ms Hazel Trender**, Vascular Clinical Nurse Specialist, Sheffield
**Mr Noel Wilson**, Consultant Vascular Surgeon, East Kent Hospitals

The GDC has significant concerns regarding the way in which the NICE senior management team has conducted itself during the development of NG 156

*"The outstanding analysis presented by the NICE technical team to the GDC, and now published for the international vascular and endovascular community to view, provides the highest quality evidence available to date with respect to AAAs."*

**Andrew W. Bradbury**

## Has Bias Played a Role?

YES

Excluding Experienced EVAR Specialists from the Guideline Development Committee is Weird

## Can RCTs be misleading

YES

The use of underpowered RCT's for EVAR performed by unexperienced Physicians to perform Novel Techniques without Proper Training and Imaging Technology, which are essential in EVAR results, must have other reasons, such as socio-economic politics

## Conclusion

Bias has definitively played a role.

The RCT's are misused in order to make it possible to come to a non-scientific conclusion which hampers innovation in the MedTec, in particularly the EVAR technology